K060269
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510(k) Summary of Safety and Effectiveness
ACMI Corporation
ACMI® DUR-Digital Ureteroscope and Choledochoscope System

General Information

Manufacturer:	ACMI Corporation 136 Turnpike Rd. Southborough, MA 01772-2104
Contact Person:	Terrence E. Sullivan Director, Regulatory Affairs Tel. #: 508-804-2739 Fax #: 508-804-2624
Date Prepared:	January 30, 2006

Device Description

Classification Name:	Endoscope and accessories (21 CFR 876.1500), Class II Surgical camera and accessories (21 CFR 878.4160), Class I
Trade Name:	ACMI® DUR-Digital Ureteroscope and Choledochoscope System (DUR®-D)
Generic/Common Name:	Endoscope, Video Camera and accessories

Predicate Devices

ACMI® Invisio™ ICN	K042225
ACMI DUR®-8E	K012925 and K023358

Intended Uses

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System (which includes the DUR-Digital Invisio™ Flexible Ureteroscope and Choledochoscope and IDC Invisio™ Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

The DUR®-D System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

Product Description

The ACMI® DUR®- Digital Ureteroscope and Choledochoscope (DUR®-D) is a flexible endoscope that incorporates CMOS (complimentary medical oxide semi-conductor) sensor technology to generate an image. There is a miniature CMOS sensor located in the distal tip, wiring running through the endoscope shaft, a printed circuit board (PCB), a light-emitting diode (LED) light source located in the handle, and an electrical cord that connects the endoscope to the Camera Control Unit.

The DUR®-Digital Ureteroscope and Choledochoscope can be introduced either through the urethra into the bladder or through a percutaneous tract into the abdominal cavity or kidney. The DUR®- Digital Ureteroscope and Choledochoscope may also be used to manage biliary calculi in a choledochoscope indication. The DUR®-D System uses a Camera Control Unit (CCU) that contains printed circuits boards (PCBs), software, power supply and power cables to process and display the images transmitted by the camera.

Technological Characteristics and Substantial Equivalence

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System, utilizes features incorporated into the following legally marketed predicate devices:

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System utilizes the same flexible endoscope technology design as those used in the predicate DUR®-8E device (K012925 and K023358).

The DUR®- Digital Ureteroscope and Choledochoscope is dimensionally similar to the predicate DUR®-8E, having the same working channel diameter and length, and utilizes the same materials in its construction as the predicate DUR®-8E.

The DUR®-Digital Ureteroscope and Choledochoscope incorporates the same basic video imaging technology located in the endoscope as the predicate ACMI® Invisio™ ICN System (K042225).

Like the predicate DUR®-8E, the ACMI® DUR®-Digital Ureteroscope and Choledochoscope (DUR®-D) System is indicated for use in therapeutic and diagnostic procedures in the entire intrarenal collecting system, and may also be used to manage biliary calculi.

During design verification, the performance of the DUR®-D was compared against the physical performance characteristics of the predicate DUR®-8E and the digital visualization characteristics of the predicate Invisio™ ICN. Testing demonstrated that the performance requirements were met, and that the DUR®-D exhibited comparable performance characteristics to both the predicate DUR®-8E and predicate Invisio™ ICN.

In summary, the ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2006

Mr. Terrence E. Sullivan
Director, Regulatory Affairs
ACMI Corporation
136 Turnpike Road
SOUTHBOROUGH MA 01772

Re: K060269
Trade/Device Name: ACMI® DUR-Digital Ureteroscope and Choledochoscope System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: FBN and FGB
Dated: January 30, 2006
Received: February 1, 2006

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: ACMI® DUR-Digital Ureteroscope and Choledochoscope System

510(k) Number: K 060269

Indications for use:

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System (which includes the DUR-Digital Invisio™ Flexible Ureteroscope and Choledochoscope and IDC Invisio™ Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

The DUR®-D System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __ **X** __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

David A. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060269